

## REMARKS

In the Office Action, claims 1-38 are rejected under 35 U.S.C. § 102 and/or under 35 U.S.C. § 103. Claims 1, 5, 17, 27, 30 and 36 have been amended; and claims 2, 3, 4, 15, 16, 22, 28, 31 and 38 have been cancelled without prejudice or disclaimer. Applicants believe that the rejections have been overcome or are improper in view of the amendments and for the reasons as set forth below.

In the Office Action, claims 1, 2, 7-10, 15, 17, 18 and 23-26 are rejected under 35 U.S.C. § 102. The Patent Office essentially asserts that the features as defined in the claims at issue are allegedly disclosed in WO 99/24145. Applicants believe that this rejection has been overcome.

At the outset, claims 2 and 15 has been canceled without prejudice or disclaimer as previously discussed. Thus, the rejection with respect to claims 2 and 15 should be rendered moot and withdrawn. Of the remaining pending claims, claims 1 and 17 are the sole independent claims at issue. Claim 1 recites an apparatus for detecting dislodgement of a needle inserted into a patient. The apparatus includes a sensor capable of detecting wetness due to blood; and a sensor holder adapted to secure the sensor in juxtaposition to the needle such that the sensor detects wetness due to blood loss from the patient upon dislodgement of the needle. Claim 1 further recites that the sensor includes a capacitive sensor as amended to include the limitation from claim 2. Claims 2-4 have been cancelled without prejudice or disclaimer and claim 5 has been amended to correct for dependency in view of same.

Claim 17 recites an apparatus for controlling blood loss from the patient during hemodialysis. The apparatus includes a sensor that is capable of detecting wetness due to blood and a sensor holder that is adapted to secure the sensor to the patient such that the sensor produces a signal indicative of wetness due to blood loss from the patient upon dislodgement of a venous needle inserted into the patient. The apparatus further includes a controller capable of processing the signal to prevent blood flow through the venous needle such that blood loss from the patient due to dislodgement of the venous needle is minimized. Claim 17 further recites that the sensor includes a capacitive sensor to include the limitation from claim 22 which has been cancelled without prejudice or disclaimer in view of same as previously discussed. Therefore, Applicants believe that the anticipation rejection in view of WO 99/24145 has been overcome.

Accordingly, Applicants respectfully request that the anticipation rejection of claims 1, 2, 7-10, 15, 17, 18 and 23-26 be withdrawn.

In the Office Action, claims 27-29, 30-34, 36 and 37 are rejected under 35 U.S.C. § 103. The Patent Office essentially asserts that WO 99/24145 discloses or suggests the claimed invention as defined by the claims at issue. Applicants believe that this rejection has been overcome.

Of the pending claims at issue, claims 27, 30 and 36 are the sole independent claims. Claim 27 recites a method of detecting needle dislodgement that includes the steps of providing a sensor capable of detecting wetness due to blood; inserting a needle into a patient; and securing the sensor to the patient such that the sensor detects blood on the patient upon dislodgement of the needle. Claim 27 further recites that the sensor includes a capacitive sensor where claim 28 was cancelled without prejudice or disclaimer in view of same and thus the rejection with respect to Claim 28 should be rendered moot and withdrawn. Claim 30 recites a method of controlling blood loss from a patient due to needle dislodgement. The method of claim 30 recites the steps of providing the sensor that is capable of detecting wetness due to blood; inserting a needle into the patient; and securing the sensor to the patient such that the sensor produces a signal indicative of wetness due to blood loss from the patient upon dislodgement of the needle; and processing the signal to prevent blood flow through the venous needle such that blood loss from the patient due to needle dislodgement is minimized. Claim 30 further recites that the sensor includes a capacitive sensor where claim 31 was cancelled without prejudice or disclaimer in view of same and thus the rejection with respect to Claim 31 should be rendered moot and withdrawn.

Claim 36 recites a method of providing dialysis to a patient. The method includes providing a sensor that is capable of detecting wetness due to blood; inserting a venous needle into the patient; securing the sensor in juxtaposition to the venous needle; passing blood through the venous needle via a hemodialysis machine; and detecting blood loss from the patient upon dislodgement of the venous needle. Claim 36 further recites that the sensor includes a capacitive sensor that does not contact blood upon detection thereof where claim 38 was cancelled without prejudice or disclaimer in view of same.

Applicants believe that the cited art is deficient with respect to the claimed invention. Indeed, the Patent Office even admits that the cited art is deficient with respect to a capacitive sensor in subsequent obviousness rejections where the Patent Office relies on an additional reference in support of each of the subsequent rejections, to allegedly remedy this deficiency as discussed below. Thus, on its own, WO 99/24145 is distinguishable from the claimed invention.

Based on at least these reasons, Applicants believe that the cited art fails to disclose or suggest the claimed invention. Therefore, Applicants respectfully submit that the cited art fails to render obvious the claimed invention.

Accordingly, Applicants respectfully request that the obviousness rejection with respect to Claims 27-29, 30-34, 36 and 37 be withdrawn.

In the Office Action, claim 35 is rejected under 35 U.S.C. § 103 as allegedly unpatentable over WO 99/24145 and further in view of WO 97/10013, Shintani et al. or JP 11-104233. The Patent Office essentially relies on a combination of references to remedy the deficiencies of WO 99/24145.

Applicants believe this rejection is improper for substantially the same reasons as discussed above. Claim 35 depends from claim 30, indirectly, and thus incorporates each of the features of claim 30. As previously discussed, the WO 99/24145, at a minimum, is deficient with respect to the capacitive sensor feature as required by the claimed invention.

Further, the Patent Office merely relies on the remaining cited art for their alleged teaching relating to closing a control valve in response to blood leakage. Therefore, even if combinable, the cited art fails to render obvious the claimed invention as defined in claim 35.

Accordingly, Applicants respectfully request that this rejection be withdrawn.

In the Office Action, claims 3, 4, 8, 9, 16, 19, 20, 22 and 25 are rejected under 35 U.S.C. § 103 as allegedly unpatentable over WO 99/24145 in view of Cox et al. ("Cox"). The Patent Office essentially relies on Cox to remedy the deficiencies of WO 99/24145.

At the outset, claims 3, 4, 16 and 22 have been canceled without prejudice or disclaimer. Thus, the rejection with respect to these claims should be rendered moot and withdrawn.

Applicants believe that this rejection is improper with respect to the remaining pending claims at issue at least for substantially the same reasons as discussed above with respect to independent claims 1 and 17. Indeed, the claims at issue depend from either of independent

claims 1 and 17 and therefore, as a matter of law, incorporate each of the features of their respective independent claims. As discussed above, the WO 99/24145 reference is clearly distinguishable with respect to the claimed invention as, at a minimum, it is deficient with respect to the claimed capacitive sensor feature.

Further, the Cox reference cannot be relied on solely to remedy the deficiencies of the primary reference. In this regard, the Patent Office merely relies on Cox with respect to this rejection for its alleged teaching regarding a loop-type resistive sensor. Therefore, even if combinable, the cited art is clearly deficient with respect to the claimed invention and thus fails to render obvious same.

Accordingly, Applicants respectfully request that the rejection with respect to Claims 3, 4, 8, 9, 16, 19, 20, 22 and 25 be withdrawn.

In the Office Action, claims 5, 6, 11-14 and 21 are rejected under 35 U.S.C. § 103 as allegedly unpatentable over WO 99/24145 in view of Johnson. The Patent Office essentially relies on Johnson to remedy the deficiencies of the WO 99/24145 reference.

Of the pending claims at issue, each depends from one of independent claims 1, 11 and 17. As previously discussed, each of these independent claims have been amended to further recite that the sensor includes a capacitive sensor. Indeed, the WO 99/24145 reference is deficient with respect to a capacitive sensor as even admitted by the patent and discussed above. Thus, on its own, WO 99/24145 is distinguishable from the claimed invention at least for these reasons.

Further, Applicants do not believe that the Patent Office can rely solely on Johnson to remedy the deficiencies of WO 99/24145. Foremost, Applicants question whether the WO 99/24145 and Johnson references can be combined in the first place. Indeed, the WO 99/24145 reference merely relates to a resistive-type sensor that is utilized to detect wetness from blood. In contrast, the primary emphasis in Johnson relates to detection of wetness in a diaper that utilizes capacitive detection where the sensor is not in contact with the wetness in the diaper that is detected. Indeed, nowhere does WO 99/24145 or the Johnson reference disclose or suggest the interchangeability between a resistive-type sensor and a capacitive-type sensor. Moreover, the detection capabilities of a sensor as applied to diaper wetness detection (i.e., Johnson) in comparison to blood leakage detection (i.e., WO 99/24145) are clearly different. Therefore,

Applicants do not believe that one skilled in the art would be so inclined to combine the teachings of WO 99/24145 and the Johnson reference for at least these reasons.

In addition, the Patent Office cannot rely solely on the Johnson reference to remedy the deficiencies of WO 99/24145, even assuming *arguendo* that the cited art can be combined in the first place. The Patent Office merely relies on Johnson for its alleged teaching regarding a capacitive-type sensor as applied to the detection of diaper wetness. In Johnson, the wet diaper detector includes an elongated strip of material sized to be positioned in a diaper with a portion of the strip residing in a region of the diaper subject to wetness and an end of the strip protruding from the diaper at the upper rear or front portion thereof. See, Johnson Abstract. Indeed, the resistive-type sensor in WO 99/24145 is merely secured to the patient with an adhesive patch 40 or a wrap-around cuff-like member 50 as shown in Figures 2 and 3, for example. Why then would one skilled in the art be motivated to replace the resistive-type sensor of WO 99/24145 with a sensor configured in an elongated material, let alone a non-contact capacitive-type, as disclosed in Johnson. Clearly, what the Patent Office has done is to apply "hindsight reasoning" in support of the modification and/or combination of WO 99/24145 and Johnson. Of course, this is not proper.

Based on at least these reasons, Applicants believe that the cited art is deficient with respect to the claimed invention. Even if combinable, Applicants believe that the cited art fails to render obvious the claimed invention.

Accordingly, Applicants respectfully request that the obviousness rejection with respect to Johnson and WO 99/24145 be withdrawn.

In the Office Action, Claim 38 is rejected as allegedly obvious in view of WO 99/24145. As previously discussed, Claim 38 has been canceled without prejudice or disclaimer. Thus, this rejection should be rendered moot. Accordingly, Applicants respectfully request that this rejection be withdrawn.

In the Office Action, claims 1, 2, 4, 5, 7-10, 15 and 16 are rejected under 35 U.S.C. § 103 as allegedly unpatentable over Cox in view of WO 99/24145. The Patent Office essentially relies on the WO 99/24145 reference to remedy the deficiencies of Cox.

Applicants believe that this rejection is improper. Of the pending claims at issue, Claims 2, 4, 15 and 16 have been canceled without prejudice or disclaimer and thus render this rejection

moot with respect to same. Of the remaining pending claims at issue, claim 1 is the sole independent claim and recites, in part, that the sensor includes a capacitive sensor as discussed above.

Contrary to the Patent Office's position, Cox is directed to a resistive-type sensor and not a "capacitive-type blood sensor". See, Office Action, p. 7, ¶ 17. Indeed, the Patent Office even alleges Cox "teaches that it is old and well known to use two loop type resistance sensors mounted on a layer of gauze to detect the [presence] of blood" in support of another obvious rejection. See, Office Action, p. 5, ¶ 9. Moreover, Cox specifically provides a pair of spaced apart wires where blood contacts the wires, allowing electrical current to flow between via the electrically conductive blood and thus supplying electricity to the alarm in order to activate it. Thus, on its own, Cox is distinguishable from the claimed invention for at least these reasons.

Further, the Patent Office cannot rely solely on WO 99/24145 to remedy the deficiencies of Cox. Indeed, WO 99/24145 is deficient with respect to a capacitive-type sensor as even admitted by the Patent Office and discussed above. Therefore, even if combinable Cox and WO 99/24145 fail to disclose or suggest the claimed invention and therefore fail to render obvious same.

Accordingly, Applicants respectfully request that the obviousness rejections with respect to Claims 1, 2, 4, 5, 7-10, 15 and 16 be withdrawn.

For the foregoing reasons, Applicants respectfully submit that the present application is in condition for allowance and earnestly solicit reconsideration of same.

Respectfully submitted,

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